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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,828	06/13/2000	Steven Rosen	6510-138US1	7507

7590 03/27/2002

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EXAMINER
MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
1652	16

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/593,828	Rosen et al.
Examiner	**Art Unit**
Maryam Monshipouri	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above, claim(s) 1-4 and 13-29 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 5-11 is/are rejected.

7) ☒ Claim(s) 12 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8&9

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Applicant's response to election of species requirement dated 1/17/02 (Paper # 15) is acknowledged. **Applicant elected Group II invention (claims 5-12) directed to GST-4α species with traverse**.

Applicant's arguments with regards to rejoining all indicated patentably distinct inventions have already been addressed in the previous office action. In traversal of species election requirement applicant argues that as stated in 37 CFR section 1.141, more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim. Accordingly, since the current pending claims are directed to a reasonable number of species, the species election requirement is not proper and should be withdrawn.

This argument was fully considered but was found unpersuasive. As stated previously, GSTα, GST β and GST-6 are directed to products of unrelated structure and function. Thus, the election of species requirement is proper because rejoining said species imposes an undue burden of searching on the examiner. Further, currently there is no allowable generic claim to all species pending. Once applicant amends the generic claims such that they will become allowable the examiner will consider examining additional species.

In conclusion, restriction of inventions and species remain as originally indicated (see paper #12) for the reasons of record in addition to those explained above and is hereby made **final.**

DETAILED ACTION

Claims 5-12 directed to GST-α species are under examination on the merits. Claims 1-4, and 13-29 are withdrawn as drawn to non-elected inventions and/or species.

Specification

The specification is objected to for having gaps such as those corresponding to ATCC deposit numbers etc. See, for example page 12 of the specification. Applicant is required to fill in all the gaps in the specification in response to this office action.

Claim Objections

1. Claim 12 is objected to under 37 CFR 1.75 (c) as being in improper form because a multiple dependent claim cannot depend on two claims simultaneously. See MPEP § 608.01(n). Accordingly, claim 12 which depends from claim 1 and 10 simultaneously, has not been further treated on the merits.

2. Claims 5-11 are objected to because of the following informalities: these claims dep end from non-elected base claim 1. Applicant is advised to rewrite claim 5 as an independent base claim. Appropriate correction is required.

3. ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "mimetic thereof" in claim 8 is indefinite. Applicant did not provide any definition for said term in the specification. Said term is usually used to refer to synthetic peptides which mimic the active site structure of proteins enzyme etc. either enhancing or inhibiting the activity of said products. Thus, it is not clear what applicant means by "mimetics "of nucleic acids. **For examination purposes said term is interpreted to mean variants (i.e. homologs, fragments etc.) of isolated nucleic acids of claim 5, encoding products with sulfotransferase activity.**

6. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "stringent conditions" in claim 8 is vague and indefinite. Applicant did not define said term specifically in the specification. In page 19 of the specification, lines 9-12 applicant provides merely, some exemplary conditions of stringent hybridization conditions. In the absence of clear and specific salt and temperature conditions used in claim 8 one of skill in the art does not know how to prepare the claimed nucleic acids and their variants (mimetics) . Applicant

is advised to recite the salt and temperature conditions used for hybridization (based on the support provided in the specification) into claim 8, in order to overcome this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 5, 7-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 5 and 7 are directed to a **genera** of isolated nucleic acids and/or fragments thereof, from any source of species which have been merely defined by function (i.e. encoding glycosyl-sulfotransferase GST-4α).

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. " A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that " in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims

encompass. accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, Applicant merely provided structure of a single species for each claimed genus , namely human GST-α (SEQ ID NO:3&4). Neither the prior art nor the specification provides any information about the structural homology that exists across the claimed DNA sequence of claim 5. Further, it is not clear wether mouse GST4 is a homolog of human GST-α or whether it is referring to an entirely unrelated sequence. Furthermore, the specification is silent about how to recognize the genus of fragments that are within the scope of claim 7 from others. Applicant is well aware that any DNA sequence consisting of 15 nucleotides (see page 13 of the specification for the definition of the term "fragment") of the nucleic acid of claim 5 is incapable of having GST-4α sulfotransferase activity. Thus, some additional information with regards to screening for fragments that are within the metes and bounds of the claimed genus (see claim 7) is required which is currently lacking in the specification. Therefore, based on the information provided a single species (i.e. human GST4-alpha, SEQ ID NO:3 or 4) does not provide an adequate written description of the genera of nucleic acids and fragments thereof as broadly claimed. Accordingly, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Since the nucleic acids of claim 5 are

inadequately described, variants thereof (claim 8) and vectors, expression cassettes and cells comprising them (claims 9-11) are also inadequately described.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 5-6, 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Bistrup et al. (U.S. Patent No. 6,265,192, issues 7/2001). Bistrup teaches and claims an isolated DNA sequence that has glycosyl sulfotransferase function. As mentioned above in claim 5 the products are merely claimed by what they encode. Since the exact functional differences between glycosyl transferase of this invention and that of Bistrup is not clear, it is reasonable to conclude that the isolated DNA sequence of Bistrup meets the limitations of claim 5. Further, the DNA sequence of Bistrup shows

34.1% identity to SEQ ID NO:4 of this invention. Due to the fact that upon changing the sequence alignment parameters Bistrup's sequence can be easily demonstrated to have at least 35% identity to SEQ ID NO:4 of this invention it is believed that Bistrup also claims a sequence that is "substantially identical" (see the definition provided in page 9 of the specification) to SEQ ID NO:4 of this invention, anticipating claim 6. Bistrup's sequence also is able to hybridize to SEQ ID NO:4 of this invention or variants (mimetic) thereof under "stringent conditions", anticipating claim 8. Similarly the expression cassettes and host cells of Bistrup (see claims 2-4) anticipate claims 9-11 of this invention respectively.

11. Claims 5-6 and 8-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al. (BBRC, 263(2), 543-549, 1999). Lee teaches an isolated DNA sequence (see the attached alignment) encoding human GST-4α which has 100% identity to SEQ ID NO:4 of this invention, which can hybridize to SEQ ID NO:4 under stringent conditions, anticipating claims 5-6 and 8. They also teach expression cassettes and host cells (i.e. COS cells) comprising said sequence (see Materials and Methods), anticipating claims 9-11 of this invention.

12. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 5 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuta et al. (J.B.C., 272(51), 32321-32328, 1997, cited in the IDS). Fukuta teaches an isolated DNA sequence encoding human sulfate Gal-6-sulfotransferase prior to this invention. As mentioned above, claim 5 is merely claiming a DNA product by function. No structural limitation of said DNA product is recited. Since the specific and exact differences between the function of Fukuta's

sulfotransferase and GST4-α of this invention is not clear it is believed that Fukuta's DNA sequence (see figure 1) meets the limitations of claims 5 and 8. In Materials and Methods section, see page 32322 column 1, Fukuta, teaches a 2415-base pair Eco RI fragment obtained from λgt11 positive clones (anticipating claim 7) and its insertion into a Bluescript plasmid which can be considered to be an expression cassette (anticipating claim 9) followed by transient expression of said fragment in COS-7 cells, anticipating claims 10-11, respectively.

14. **No claims are allowed.**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308- 1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Maryam Monshipouri, Ph.D.

Patent Examiner